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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ALTANA PHARMA AG and WYETH, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., et al., Defendants.	Civil Action No. 04-2355 (JLL) **OPINION**

LINARES, District Judge.

This matter comes before the Court by way of motions for partial summary judgment related to the issue of patent misuse filed by Plaintiffs and Defendants, respectively [Docket Entry Nos. 1121 and 1137]. Plaintiffs' motion seeks: (a) dismissal of Defendants' temporal scope patent misuse defense, and (b) dismissal of Defendants "bundling" defense. Defendants' motion seeks a ruling that the patent-in-suit is unenforceable due to Plaintiffs' patent misuse. The Court has considered the submissions made in support of and in opposition to both motions, and decides them together inasmuch as both relate to the defense of patent misuse. No oral argument was heard. Fed. R. Civ. P. 78. Based on the reasons that follow, Plaintiffs' motion [1121] is **granted** and Defendants' motion [1137] is **denied.**

BACKGROUND

1. *General*

This is a patent infringement action to enforce United States Patent No. 4,758,579 ("the '579 patent"). The asserted claims of the '579 patent – claims 22 and 25 – cover a chemical compound named Pantoprazole, and its sodium salt, pantoprazole sodium. Pantoprazole is the active ingredient in PROTONIX®, a drug manufactured for the treatment of gastric acid disorders (hereinafter referred to as "Protonix"). Plaintiff Nycomed GmbH (formerly known as Altana Pharma AG and, at the time of the invention, Byk Gulden) owns the '579 patent. Plaintiff Wyeth (formerly known as American Home Products Corporation) markets and sells Protonix in the United States as Nycomed's exclusive licensee.

Protonix was approved by the FDA on February 2, 2000 and was first marketed to the public in 2000. Defendants Teva, Sun and KUDCo each filed an Abbreviated New Drug Application ("ANDA") pursuant to the Hatch-Waxman Act, seeking FDA approval to sell a generic version of Protonix prior to the expiration of the '579 patent.

In May of 2004, Plaintiffs responded by suing Teva, Sun and KUDCo for infringement of the '579 patent. In addition to seeking equitable relief, Plaintiffs seek lost profits damages and/or reasonable royalty damages pursuant to 35 U.S.C. § 284.

Plaintiffs' motion for a preliminary injunction was denied in September 2007. Defendants Teva and Sun subsequently launched generic pantoprazole products "at risk," i.e., before entry of final judgment on the merits of this litigation, and before the patent expired. Sun, Teva and KUDCo each stipulated to infringement of claims 22 and 25 of the '579 patent *if* those claims were ultimately found to be valid and enforceable.

A jury trial was conducted for several weeks in April 2010 with respect to Defendant Teva and Defendant Sun's affirmative defenses and counterclaims that claims 22 and 25 of the '579 patent are invalid for obviousness and obviousness-type double patenting. Simultaneously, a non-jury trial was conducted with respect to Defendant KUDCo's affirmative defenses and counterclaims. The jury returned a verdict in favor of Plaintiffs as to each issue tried. On July 15, 2010, the Court issued a bench opinion as to Defendant KUDCo. The Court ruled that KUDCo had not demonstrated by clear and convincing evidence that the asserted claims of the '579 patent are invalid either for obviousness under 35 U.S.C. § 103 or under the judicially created doctrine of obviousness-type double patenting. The parties subsequently began discovery on the remaining issues in the case—damages and Defendants' claims of unenforceability.

The '579 patent expired on July 19, 2010. The FDA awarded Wyeth a period of pediatric exclusivity that expired on January 19, 2011.

2. *Pending Motions*

Both sides move for partial summary judgment on Defendants' affirmative defense of patent misuse. Defendants' theory of misuse is that Nycomed and Wyeth entered into an agreement—the "Ninth Amendment"—that operated in every way as if the '579 patent expired six months *after* its expiration date. In particular, Defendants point out that, pursuant to the terms of the Ninth Amendment, Wyeth paid royalties to Nycomed for the use of the '579 patent for six months after its expiration. Such agreement, according to the Defendants, constitutes patent misuse *per se*.

The parties agree, as a general matter, that a patentee may not extend the temporal scope of a patent beyond the statutory grant.[1] The parties dispute, however: (a) whether a showing of patent leverage is required to establish *per se* patent misuse, and if so, how the element of leverage is defined, and (b) whether a finding of *per se* patent misuse renders unenforceable either the post-expiration royalty provision or the patent itself.

LEGAL STANDARD

Summary judgment is appropriate when, drawing all reasonable inferences in the non-movant's favor, there exists no "genuine dispute as to any material fact" and the movant is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(a); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986); *King Pharm., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1273 (Fed. Cir. 2010).

The moving party is entitled to judgment as a matter of law when the non-moving party fails to make "a sufficient showing on an essential element of her case with respect to which she has the burden of proof." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). However, if a reasonable juror could return a verdict for the non-moving party regarding material disputed factual issues, summary judgment is not appropriate. *See Anderson*, 477 U.S. at 242-43 ("At the summary judgment stage, the trial judge's function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial."). With this framework in mind, the Court turns now to the pending motions.

[1] *See Brulotte v. Thys Co.*, 379 U.S. 29, 32 (1964) ("[W]e conclude that a patentee's use of a royalty agreement that projects beyond the expiration date of the patent is unlawful per se.").

ANALYSIS

1. *Defendants' Motion*

Defendants have asserted a temporal scope patent misuse defense in this action. According to Defendants, the Ninth Amendment and, in particular, the six months of additional royalty payments it provided for, constituted *per se* patent misuse under *Brulotte v. Thys Co.*, 379 U.S. 29 (1964), because the amendment unlawfully extended the temporal scope of the '579 patent. As a result of this extension, Defendants maintain that the '579 patent is unenforceable as of January 1, 2009—the date on which the Ninth Amendment went into effect—and Defendants are thus relieved from liability for damages that accrued after January 1, 2009.

Defendants maintain that the collection of royalties on a patent that has expired constitutes patent misuse *per se* under *Brulotte*. Defendants further maintain *per se* misuse does not require a showing of patent leverage (or coercion). (Def. Reply at 6).[2] As a result, Defendants' motion is based entirely on the premise that the collection of royalties on a patent that has expired—alone—constitutes patent misuse *per se*. In light of Defendants' theory, Defendants essentially concede that if the Court finds that patent leverage (to the extent it is defined by the Court as something more than "a nexus between the patent and the misconduct in question") *is* required to sustain the affirmative defense of *per se* patent misuse, then a grant of summary judgment in its favor is inappropriate. *See* Def. Opp'n Br. at 14, 17 ("Even if coercion

[2] The parties agree that Defendants need not show anticompetitive effects to sustain a defense of *per se* misuse. *See, e.g., Windsurfing Int'l, Inc. v. AMF, Inc.*, 782 F.2d 995, 1001-1002 (Fed. Cir. 1986) ("To sustain a misuse defense involving a licensing arrangement **not** held to have been per se anticompetitive by the Supreme Court, a factual determination must reveal that the overall effect of the license tends to restrain competition unlawfully in an appropriately defined relevant market.") (emphasis added).

were an element of *Brulotte*-type misuse (which it is not), there exist factual disputes precluding summary judgment in Plaintiffs' favor."). Thus, as a preliminary matter, the Court turns to the following two legal questions: (1) whether patent leverage is required to sustain a *per se* patent misuse defense, and if so, (2) what constitutes patent leverage.

A. ***Per Se* Misuse**

Generally speaking, patent misuse is an affirmative defense to an accusation of patent infringement, the successful assertion of which "requires that the alleged infringer show that the patentee has impermissibly broadened the 'physical or temporal scope' of the patent grant with anticompetitive effect." *Windsurfing Int'l, Inc. v. AMF, Inc.*, 782 F.2d 995, 1001 (Fed. Cir. 1986).

"[T]he key inquiry under the patent misuse doctrine is whether, by imposing the condition in question, the patentee has impermissibly broadened the physical or temporal scope of the patent grant and has done so in a manner that has anticompetitive effects." *Princo Corp. v. Int'l Trade Comm'n,* 616 F.3d 1318, 1328 (Fed. Cir. 2010). In cases "where the patentee has not leveraged its patent beyond the scope of rights granted by the Patent Act, misuse has not been found." *Id.* In this regard, the Federal Circuit has explained:

> What patent misuse is about, in short, is "'patent leverage," i.e., the use of the patent power to impose overbroad conditions on the use of the patent in suit that are "not within the reach of the monopoly granted by the Government." What that requires, at minimum, is that the patent in suit must "itself significantly contribute[ ] to the practice under attack." Patent misuse will not be found when there is "no connection" between the patent right and the misconduct in question, or no "use" of the patent.

Id. at 1331 (citations omitted).

Courts have identified certain specific practices as constituting *per se* patent misuse, including "tying" arrangements in which a patentee conditions a license under the patent on the purchase of a separate product, and arrangements in which a patentee effectively extends the term of its patent by requiring post-expiration royalties. *See Virginia Panel Corp. v. MAC Panel Co.*, 133 F.3d 860, 868-869 (Fed. Cir. 1997). Evidence of anticompetitive effects need not be shown where the practice at issue constitutes *per se* patent misuse. *See, e.g., Windsurfing,* 782 F.2d at 1001-1002 ("To sustain a misuse defense involving a licensing arrangement not held to have been per se anticompetitive by the Supreme Court, a factual determination must reveal that the overall effect of the license tends to restrain competition unlawfully in an appropriately defined relevant market.").

In *Brulotte v. Thys Co.,* a suit brought by the owner of a patent to recover royalty payments, the United States Supreme Court held that "a patentee's use of a royalty agreement that projects beyond the expiration date of the patent is unlawful *per se*." 379 U.S. 29, 32-33 (1964). The defendant licensee in that case had refused to make royalty payments that accrued both before and after the expiration of the plaintiff's patents. In holding unenforceable defendant's obligation to make royalty payments after patent expiry, the Court explained:

> A patent empowers the owner to exact royalties as high as he can negotiate with the leverage of that monopoly. But to use that leverage to project those royalty payments beyond the life of the patent is analogous to an effort to enlarge the monopoly of the patent by tieing the sale or use of the patented article to the purchase or use of unpatented ones.

Brulotte, 379 U.S. at 33.

Although Defendants urge the Court to read *Brulotte* as holding that neither coercion nor patent leverage are elements of a *per se* patent misuse defense, the Supreme Court has since

confirmed that the post-expiry royalty obligations found to have constituted *per se* misuse in *Brulotte* had, in fact, been negotiated "with the leverage of the patent." *See Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 264-65 (1979). In *Aronson*, the Supreme Court explained:

> Enforcement of the royalty agreement here is also consistent with the principles treated in *Brulotte v. Thys Co.*, 379 U.S. 29 (1964). There, we held that the obligation to pay royalties in return for the use of a patented device may not extend beyond the life of the patent. The principle underlying that holding was simply that the monopoly granted under a patent cannot lawfully be used to "negotiate with the leverage of that monopoly." The Court emphasized that to "use that leverage to project those royalty payments beyond the life of the patent is analogous to an effort to enlarge the monopoly of the patent . . . ." *Id.* at 33, Here the reduced royalty which is challenged, far from being negotiated "with the leverage" of a patent, rested on the contingency that no patent would issue within five years.

Id. Thus, the Court finds that in order to sustain an affirmative defense of *per se* patent misuse, Defendants must show that the Ninth Amendment—which obligated Wyeth to make post-expiry royalty payments—was negotiated by Plaintiffs with the leverage of the '579 patent. *See Aronson,* 440 U.S. at 264-65 (finding royalty agreement enforceable, even once the pending patent application was rejected, where the reduced royalty provision at issue, which expressly recognized the possibility that no patent may issue, was "far from being negotiated with the leverage of a patent"); *Brulotte*, 379 U.S. at 32 (finding post-expiration royalty agreement unenforceable as constituting *per se* patent misuse and noting that "[w]e are . . . unable to conjecture what the bargaining position of the parties might have been and what resultant arrangement might have emerged had the provision for post-expiration royalties been divorced from the patent and nowise subject to its leverage.").

i. *Patent Leverage*

Having determined that patent leveraging is an element of *per se* patent misuse, the Court now turns to the issue of what exactly constitutes patent leveraging. The Federal Circuit has defined patent leverage as "the use of the patent power to impose overbroad conditions on the use of the patent in suit that are 'not within the reach of the monopoly granted by the Government.' What that requires, at minimum, is that the patent in suit must 'itself significantly contribute[ ] to the practice under attack.' " *Princo*, 616 F.3d at 1331. In this regard, this Court has previously held that "patent leverage is conditioning access to a patent on some demand by the patentee." *See* Tr. (Sept. 29, 2011 Op.) at 12:8-9.

Defendants urge the Court to read *Princo* as holding that patent leverage, to the extent it is a required element of *per se* patent misuse, is simply the existence of a nexus between the patent and the unlawful conduct. (Def. Reply at 6). In support of this position, Defendants refer to the following excerpt from *Princo*:

> Patent misuse will not be found when there is "no connection" between the patent right and the misconduct in question, or no "use" of the patent. In this case, there is no such link between the putative misconduct and the Raaymakers patents.

Princo, 616 F.3d at 1331-32 (internal citations omitted). The Court does not read this language, stating what patent misuse is *not,* as suggestive of the converse—what patent misuse *is*. Certainly, the Court does not read this excerpt as defining patent *leverage* as simply a nexus between the patent and the unlawful conduct. This is particularly so given the express definition of "patent leverage" provided by the *Princo* Court in the sentences preceding that excerpt. *See Princo*, 616 F.3d at 1331 ("What patent misuse is about, in short, is 'patent leverage,' i.e., the

use of the patent power to impose overbroad conditions on the use of the patent in suit that are 'not within the reach of the monopoly granted by the Government.' ").

Thus, the Court finds that patent leverage *is* a required element of *per se* patent misuse, and that patent leverage is defined as conditioning access to a patent on some demand by the patentee. *See* Tr. (Sept. 29, 2011 Op.) at 12:8-9; *see also Princo*, 616 F.3d at 1331. Because Defendants do not even attempt to show the required element of patent leverage, as defined above,[3] Defendants' motion for summary judgment, seeking a ruling that the '579 patent is unenforceable due to Plaintiffs' patent misuse, is denied.

2. *Plaintiffs' Motion*

Plaintiffs move for partial summary judgment on two issues: (1) dismissing Defendants' affirmative defense of *per se* patent misuse, and (2) dismissing Defendants' "bundling" defense. The Court will address each issue, in turn.

A. **Facts**

i. *Patent Misuse*

The asserted claims of the '579 patent cover the compound pantoprazole and its sodium salt. (SUMF, ¶ 1; RSUMF, ¶ 1).[4] Nycomed owns the '579 patent. (SUMF, ¶ 2; RSUMF, ¶ 2). Wyeth agreed to jointly develop and commercialize pantoprazole in the United States under the

[3] *See* Def. Reply Br. at 6 ("Coercion (whether Plaintiffs call it that or 'conditioning' or 'leverage') is not an element of a *Brulotte*-type misuse defense."); *id.* ("To the extent that 'patent leverage' has to be shown in a per se misuse case, it simply requires showing a sufficient nexus between the patent and the unlawful conduct.").

[4] "SUMF" refers to Plaintiff's Rule 56.1 Statement of Undisputed Facts. "RSUMF" refers to Defendants' Response to Plaintiff's Rule 56.1 Statement of Undisputed Facts.

brand name Protonix beginning in the 1990s. (SUMF, ¶ 3; RSUMF, ¶ 3). From the outset, Wyeth and Nycomed intended a long-term collaboration to commercialize branded pantoprazole from the period before FDA approval, through the exclusivity period afforded them by the '579 patent. (SUMF, ¶ 4; RSUMF, ¶ 4). In 1996, Wyeth and Nycomed entered into an agreement (hereinafter referred to as the "License Agreement") that set forth the companies' respective responsibilities and contributions to the joint development and commercialization effort. (SUMF, ¶ 5; RSUMF, ¶ 5). As described in the preamble to the License Agreement:

> In order to be able to launch Pantoprazole in the United States, [Nycomed] is in need of the assistance of a strong partner capable of developing, marketing and distributing Pantoprazole in the United States. ... [Wyeth] is interested in cooperating with [Nycomed] in the development, marketing and sales of Pantoprazole in the United States on a long-term basis and is therefore not only interested in a license to the Product and the Compound during Patent protection, but also interested in assuring itself of a long-term source of supply of the Compound before and after Patent expiry[.]

(*Id.*).

Under the 1996 License Agreement, Nycomed granted Wyeth an exclusive license to market a finished prescription pantoprazole product for human use in the United States using pantoprazole compound and/or bulk products supplied by Altana or its appointees. (SUMF, ¶ 6; RSUMF, ¶ 6). Wyeth's exclusive license to the '579 patent ran through patent expiry. (SUMF, ¶ 7; RSUMF, ¶ 7).

Wyeth and Nycomed agreed to collaborate on developing and obtaining approval for pantoprazole, including undertaking studies and testing necessary to obtain approval from the FDA to market Protonix through a New Drug Application (NDA) for Protonix (pantoprazole sodium), as well as Supplemental New Drug Applications (SNDA) for other formulations of Protonix, including an intravenous product. (SUMF, ¶ 8; RSUMF, ¶ 8).

After the 1996 agreement was executed, Wyeth's wholly-owned subsidiary Wyeth Pharmaceuticals, Inc. obtained FDA approval to market Protonix through an NDA for Protonix (pantoprazole sodium). (SUMF, ¶ 12; RSUMF, ¶ 12). Wyeth sells Protonix in the United States. (SUMF, ¶ 13; RSUMF, ¶ 13). Under the 1996 License Agreement, Wyeth agreed to pay Nycomed 25 percent of Wyeth's net sales of Protonix during the time period the patent was in force. (SUMF, ¶ 14; RSUMF, ¶ 14).

On January 29, 2008, Wyeth and Nycomed entered into the "Panto Generic Letter Agreement," which established terms under which Wyeth would launch a non-branded version of pantoprazole. (SUMF, ¶ 15; RSUMF, ¶ 15). Under the Panto Generic Letter Agreement, Nycomed received 36 percent of Wyeth's quarterly net profit (as defined in the agreement) on sales of non-branded generic pantoprazole products. (SUMF, ¶ 16; RSUMF, ¶ 16).

Under the Food and Drug laws, NDA holders that engage in clinical testing of a drug in the pediatric population can be entitled to obtain an additional period of exclusivity after patent expiry, during which the FDA will not approve applications from other companies to market the drug. (SUMF, ¶ 17; RSUMF, ¶ 17). At the FDA's request, Wyeth performed clinical testing of pantoprazole in pediatric populations, and on February 17, 2009, Wyeth received a grant of pediatric exclusivity from the FDA on pantoprazole for having performed those studies. (SUMF, ¶ 18; RSUMF, ¶ 18). Pediatric exclusivity began after expiration of the '579 patent on July 19, 2010, and ended on January 19, 2011. (SUMF, ¶ 20; RSUMF, ¶ 20).

Wyeth and Nycomed executed the Ninth Amendment to the License Agreement on April 30, 2009; the Ninth Amendment was made effective as of January 1, 2009. (SUMF, ¶ 23; RSUMF, ¶ 23). In the Ninth Amendment, the companies, *inter alia*, updated the pertinent terms of the original 1996 license to reflect the pediatric exclusivity extension on pantoprazole

awarded in 2009, which included addressing the parties' respective obligations during the period of pediatric exclusivity. (SUMF, ¶ 24; RSUMF, ¶ 24). In addition, the Ninth Amendment renewed and modified the parties' agreement with respect to the generic pantoprazole product that Wyeth had launched purportedly in response to Defendants' infringing pantoprazole products. (SUMF, ¶ 25; RSUMF, ¶ 25). The Ninth Amendment also changed the license's provisions regarding Nycomed's manufacture of pantoprazole tablets for Wyeth. (SUMF, ¶ 26; RSUMF, ¶ 26). Finally, the Ninth Amendment extended the established royalty provisions for the six-month period of pediatric exclusivity, including the requirement of Wyeth to pay Nycomed a 5% patent royalty for use of the '579 patent. (SUMF, ¶ 27; RSUMF, 27).

At the time the Ninth Amendment was negotiated and entered into, Wyeth already had certain exclusive rights under the '579 patent, including the right to sell a prescription pantoprazole product for human use under the Protonix trademark through patent expiration. (SUMF, ¶ 28; RSUMF, ¶ 28).

ii. *Facts Relevant to "Bundling"*

Plaintiffs seek damages for Defendants' infringement beginning in late 2007. (SUMF, ¶ 40; RSUMF, ¶ 40).

Between 2001 and 2006, Wyeth pursued a strategy to sell Protonix Oral and Protonix I.V. to hospitals at discounted prices under the same hospital contracts. (SUMF, ¶ 30; RSUMF, ¶ 30). Defendants refer to Wyeth's use of these hospital contracts as a "bundling" strategy. (SUMF, ¶ 31; RSUMF, ¶ 31).

Civil actions alleging violations of the False Claims Act have been filed against Wyeth in the United States District Court for the District of Massachusetts by the United States, as well as

relators and state attorneys general, related to the relationship between Wyeth's hospital pricing and Wyeth's Medicaid rebates. (SUMF, ¶ 32; RSUMF, ¶ 32). The government's complaint alleges that, between mid-2001 and 2006, Wyeth knowingly reported to state Medicaid agencies an incorrect "Best Price" for Protonix and thereby failed to pay sufficient Medicaid rebates during this time because it failed to properly account for its hospital pricing. (SUMF, ¶ 33; RSUMF, ¶ 33). The government's contention in the Massachusetts case is that Wyeth knowingly breached its "legal obligation to make accurate quarterly reports to CMS of the Best Prices in the prior quarter for each of its drug products, including Protonix Oral and Protonix I.V." (SUMF, ¶ 34; RSUMF, ¶ 34).

The expert report submitted by Teva's damages expert, Dr. Ryan Sullivan, provides, in pertinent part:

> I understand that the District Court for the District of New Jersey (Judge Hochberg) has held that "[i]t is beyond dispute that a plaintiff cannot recover lost profits that are predicated on the completion of illegal activity." I further understand that the legality of Wyeth's use of the bundling strategy is currently pending before Judge Woodlock of the federal District Court for the District of Massachusetts, and that, if he concludes that some portion of sales are attributable to illegal conduct, then the jury may consider that evidence as one of the many complex factors it will weigh in calculating the appropriate damages in this case.

(SUMF, ¶ 36; RSUMF, ¶ 36); (Ruiz Decl., Ex. 14, ¶ 169). Dr. Sullivan asserts that he calculates the amount of sales that Wyeth would have made in the absence of infringement and then subtracts from the total sales volume those sales which Dr. Sullivan contends are attributable to "bundling;" this reduced sales base is Dr. Sullivan's alternative base for calculating lost profit damages, leading to a nearly 40 percent reduction in his calculated damages. (SUMF, ¶ 37; RSUMF, ¶ 37).

The False Claims Act cases brought against Wyeth are in pre-trial proceedings. (SUMF, ¶ 41; RSUMF, ¶ 41). Wyeth has filed motions for summary judgment in the False Claims Act cases. To date, such motions remain pending and no trial date has been set in any of the False Claims Act cases. (SUMF, ¶¶ 42, 43; RSUMF, ¶¶ 42, 43).

B. **Analysis**

i. *Patent Misuse*

Plaintiffs seek dismissal of Defendants' affirmative defense of *per se* patent misuse based on, *inter alia*, Defendants' failure to show the required element of patent leverage. In particular, Plaintiffs maintain that Defendants' claim of misuse fails inasmuch as Defendants have failed to show that the post-expiration royalty provision provided for by the Ninth Amendment was negotiated with the leverage of the '579 patent.

As previously stated, patent leverage is defined as conditioning access to a patent on some demand by the patentee. *See* Tr. (Sept. 29, 2011 Op.) at 12:8-9; *see also Princo*, 616 F.3d at 1331. Thus, in order establish a claim of *per se* patent misuse, Defendants must show that Nycomed conditioned Wyeth's license to the '579 on Nycomed's demand for post-expiration royalties. *See Brulotte*, 379 U.S. at 32 (finding post-expiration royalty agreement unenforceable as constituting *per se* patent misuse where the provision for post-expiration royalties was not "divorced" from the patent and was, instead, "subject to its leverage.").

There is no dispute that by the time Wyeth agreed to pay post-expiration royalties (April 2009),[5] it already had the exclusive right—by virtue of the 1996 License Agreement—to sell prescription pantoprazole for human use under the Protonix trademark, using API and/or bulk

[5] (SUMF, ¶ 23; RSUMF, ¶ 23).

product supplied by Nycomed or its appointees, through patent expiry.[6] Thus, based on the current record, it cannot be said that Nycomed conditioned Wyeth's access to the '579 patent, on its demand for post-expiration royalties.

In opposition to Plaintiffs' motion, Defendants argue that there are factual disputes precluding summary judgment. In particular, Defendants point to two alleged factual disputes. First, Defendants claim that the very fact that Wyeth would have had no pediatric exclusivity to enjoy without access to Nycomed's patent shows that Nycomed was in a position to use its control over the patent as leverage in negotiating with Wyeth. (Def. Opp'n Br. at 18). This theory, based on nothing more than speculation, does not create a triable issue of fact. *See, e.g., Novartis Corp. v. Ben Venue Labs., Inc.*, 271 F.3d 1043, 1051 (Fed. Cir. 2001) ("'[T]heoretical speculations' lacking a basis in the record will not create a genuine issue of fact.") (quoting *Penn. Dental Ass'n v. Med. Serv. Ass'n*, 745 F.2d 248, 262 (3d Cir. 1984)).

Next, Defendants argue that Nycomed used as leverage its consent to Wyeth's marketing of an authorized generic; this consent was not provided for under the terms of the 1996 License Agreement. (Def. Opp'n Br. at 18). But Defendants concede that Nycomed's "consent" was, as a general matter, provided for in the Panto Generic Letter Agreement, which was entered into by Nycomed and Wyeth in January 2008—over a year *before* the same parties executed the Ninth Amendment, which included the post-expiration royalty provision at issue.[7] Defendants maintain, however, that in late 2008, Nycomed was refusing to negotiate an extension of the Panto Generic Letter Agreement and that the parties ultimately agreed to the Ninth Amendment, which extended the Panto Generic Letter Agreement, on January 1, 2009—the date the Panto

[6] (SUMF, ¶ 28; RSUMF, ¶ 28).

[7] (SUMF, ¶¶ 15, 16; RSUMF, ¶¶ 15, 16).

Generic Letter Agreement would have expired. Defendants thus extrapolate that "[i]t is reasonable to conclude that [Nycomed] used its stronger bargaining position as the patentee to force Wyeth to accept terms favorable to [Nycomed], including payment of post-expiration royalties . . . ." (Def. Opp'n Br. at 18).

In support of this argument, Defendants rely on two documents: (1) an internal Wyeth document indicating its proposal to finalize and execute a "long-term Panto Letter Agreement,"[8] and (2) an e-mail correspondence between Jay Bowsher of Wyeth and Gerhard Passet of Nycomed wherein Mr. Passet states that "[i]nternal discussions indicate high reluctance to extend the og-agreement by a quarter . . . "[9]

As a preliminary matter, both documents relate entirely to the issue of whether the parties would agree to extend the Panto Generic Letter Agreement. Neither document, on its face, even mentions the period of pediatric exclusivity or the potential for any post-expiration royalty payments related thereto. Certainly, neither document presents direct evidence of Nycomed's attempt to condition use of the '579 patent on the payment of post-expiration royalties. Defendants do not dispute this. *See* Def. Opp'n Br. at 18.

At most, Defendants attempt to show that Nycomed leveraged its "stronger bargaining position" as the patent holder to force Wyeth to accept terms favorable to Nycomed—including payment of post-expiration royalties. *See* Def. Br. at 18 (referring to the foregoing documents, and noting that "[i]t is [therefore] reasonable to conclude that Altana used its stronger bargaining position as the patentee to force Wyeth to accept terms favorable to Altana, including payment of post-expiration royalties and treating the patent as if it had a longer life than it actually did.").

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[8] (Rozendaal Decl., Ex. B, W05598924).

[9] (Rozendaal Decl., Ex. C, W14888538).

Even assuming, *arguendo*, that it were sufficient to show that Nycomed leveraged its "bargaining position" as the patent holder—which it is ***not***[10]— Defendants have come forward with no evidence suggesting, much less demonstrating, that Nycomed conditioned the extension of the Panto Generic Letter Agreement on the execution of the Ninth Amendment—or even attempted to do so. Stated differently, Defendants have come forward with ***no*** evidence tying together Nycomed's "reluctance" to extend the Panto Generic Letter Agreement with Wyeth's agreement to pay post-expiration royalties. Absent a sufficient nexus between the two, this Court finds that no reasonable jury could conclude that Nycomed conditioned (or attempted to condition) the extension of the Panto Generic Letter Agreement—by virtue of its alleged superior bargaining position, or otherwise—on Wyeth's agreement to make post-expiration royalty payments.

In conclusion, Defendants maintain that the Ninth Amendment and, in particular, the six months of additional royalty payments it provided for, constituted *per se* patent misuse under *Brulotte* because the amendment unlawfully extended the temporal scope of the '579 patent. In order to sustain an affirmative defense of *per se* patent misuse, Defendants must show that the post-expiration royalty provision contained in the Ninth Amendment was negotiated by Nycomed with the leverage of the '579 patent. Patent leverage is defined as conditioning access to a patent on some demand by the patentee. *See* Tr. (Sept. 29, 2011 Op.) at 12:8-9; *see also*

[10] *See Aronson,* 440 U.S. at 264-265 (finding royalty agreement enforceable, even once the pending patent application was rejected, where the reduced royalty provision at issue, which expressly recognized the possibility that no patent may issue, was "far from being negotiated with the leverage **of a patent**") (emphasis added); *Brulotte*, 379 U.S. at 32 (finding post-expiration royalty agreement unenforceable as constituting *per se* patent misuse and noting that "[w]e are . . . unable to conjecture what the bargaining position of the parties might have been and what resultant arrangement might have emerged had the provision for post-expiration royalties been divorced **from the patent** and nowise subject to **its leverage**.") (emphasis added).

Princo, 616 F.3d at 1331. Thus, to succeed on their affirmative defense of *per se* patent misuse, Defendants must show that Nycomed conditioned Wyeth's access to the '579 patent on Nycomed's demand for post-expiration royalty payments.

Evidence in the record shows that by the time Wyeth agreed to pay post-expiration royalties (April 2009),[11] it already *had* the exclusive right—by virtue of the 1996 License Agreement—to sell prescription pantoprazole for human use under the Protonix trademark through patent expiry (July 2010).[12] In opposition to Plaintiffs' motion, Defendants have come forward with no evidence upon which a reasonable jury could nevertheless conclude that Nycomed conditioned Wyeth's access to the '579 patent on Wyeth's agreement to pay post-expiration royalties. Without such evidence of patent leverage, Defendants' affirmative defense of *per se* patent misuse fails as a matter of law. *See Aronson,* 440 U.S. at 264-265; *Brulotte*, 379 U.S. at 32. Plaintiffs' motion for summary judgment as to this affirmative defense is therefore **granted.**[13]

ii. *Bundling*

Defendants previously asserted in this action an affirmative defense of patent misuse based on Plaintiffs' alleged "Medicaid fraud." In particular, Teva claimed that Wyeth used the leverage of the '579 patent to suppress competition from non-patented proton pump inhibitors by, *inter alia*, withholding discounts from hospitals unless the hospitals entered into agreements with Wyeth, whereby hospitals were required to purchase *both* the intravenous form of Protonix

[11] (SUMF, ¶ 23; RSUMF, ¶ 23).

[12] (SUMF, ¶ 28; RSUMF, ¶ 28).

[13] Thus, the Court need not reach the issue of whether a finding of *per se* patent misuse renders unenforceable the '579 patent, itself, or only the post-expiration royalty provision at issue.

bundled and the tablet form, together, while simultaneously agreeing to refrain from purchasing other companies' proton pump inhibitor pills. On February 28, 2011, this Court struck Defendants' "Medicaid theory of patent misuse," without prejudice, finding that Defendants had failed to sufficiently articulate how Wyeth used the power of the '579 patent to influence third parties to participate in the alleged rebating scheme. On April 2, 2011, Defendants re-pled their "Medicaid theory of patent misuse." On September 29, 2011, this Court struck these allegations, *with* prejudice, finding, in pertinent part, that Defendants had failed to allege how Plaintiffs' ability to offer discounted bundling prices depended on the power of the '579 patent. *See* Tr. (Sept. 29, 2011) at 12:16-25.

The expert report submitted by Teva's damages expert, Dr. Ryan Sullivan, seeks to reduce Plaintiffs' damages in this action by as much as 40% based on the theory that a significant portion of the Protonix sales at issue are attributable to illegal conduct—namely, Wyeth's "bundling" strategy. Dr. Sullivan's report provides as follows:

> I understand that the District Court for the District of New Jersey (Judge Hochberg) has held that "[i]t is beyond dispute that a plaintiff cannot recover lost profits that are predicated on the completion of illegal activity." I further understand that the legality of Wyeth's use of the bundling strategy is currently pending before Judge Woodlock of the federal District Court for the District of Massachusetts, and that, if he concludes that some portion of sales are attributable to illegal conduct, then "the jury may consider that evidence as one of the many complex factors it will weigh in calculating the appropriate damages in this case.

(SUMF, ¶ 36; RSUMF, ¶ 36); (Ruiz Decl., Ex. 14, ¶ 169). Thus, Dr. Sullivan calculates the amount of sales that Wyeth would have made in the absence of infringement and then subtracts from the total sales those sales which he contends are attributable to "bundling," resulting in a nearly 40 percent reduction in his calculated damages. (SUMF, ¶ 37; RSUMF, ¶ 37).

Plaintiffs urge the Court to preclude Defendants from attempting to limit any award of damages based upon allegations of Wyeth's Medicaid fraud or Wyeth's "bundling" strategy for two reasons: (1) Defendants do not argue that the sales of Protonix that Wyeth would have made in the absence of infringement were, themselves, "illegal," and (2) even if Defendants' theory had merit, Defendants have provided no facts to support it; rather, they rely on mere allegations made in an unrelated proceeding for the proof necessary to defeat summary judgment in this matter.

By way of background, the Court notes that civil actions alleging violations of the False Claims Act have been filed against Wyeth in the United States District Court for the District of Massachusetts by the United States, as well as relators and state attorneys general, related to the relationship between Wyeth's hospital pricing and Wyeth's Medicaid rebates (collectively referred to as the "False Claims Act cases"). The government's complaint in that action alleges that, between mid-2001 and 2006, Wyeth knowingly reported to state Medicaid agencies an incorrect "Best Price" for Protonix and thereby failed to provide Medicaid with the same "bundling" discounts it was offering hospitals. (Ex. 4 to Teva's Fourth Amended Answer and Counterclaims, Docket Entry No. 1054). Thus, the crux of the government's complaint in the Massachusetts action is that, "by reporting false and inflated Best Prices, Wyeth improperly reduced its rebate payments by hundreds of millions of dollars and denied Medicaid the benefit of the low prices it was offering to thousands of hospitals," in violation of the False Claims Act and the common law. (*Id.*). Wyeth has filed motions for summary judgment in the False Claims Act cases. To date, such motions remain pending and no trial date has been set in any of the False Claims Act cases. (SUMF, ¶¶ 42, 43; RSUMF, ¶¶ 42, 43).

The Court begins by noting that Dr. Sullivan's theory is premised—*entirely*—on the notion that the legality of Wyeth's use of the bundling strategy is at issue and currently pending in the Massachusetts action. But it is not. The claims filed in the Massachusetts action question the legality of Wyeth's reporting practices vis-à-vis the Medicaid Drug Rebate Program ("MDRP"), which, according to the government, obligated Wyeth to report to the Secretary of Health and Human Services ("Secretary") on a quarterly basis the Average Manufacturer Price ("AMP") and "Best Price" for Protonix. (Ex. 4 to Teva's Fourth Amended Answer and Counterclaims, Docket Entry No. 1054 at 1) ("The United States brings this action to recover hundreds of millions of dollars that defendant Wyeth failed to pay the Medicaid program by knowingly reporting false and fraudulent prices for its two types of acid suppressant drugs, Protonix tablets ("Protonix Oral") and intravenous Protonix ("Protonix IV").")

For instance, Count One ("False Claims Act, 31 U.S.C. § 3729(a)(1)(1986)") of the Government's Complaint alleges that:

> From the second quarter of 2001 and continuing through the fourth quarter of 2006, Wyeth provided false quarterly submissions to [Centers for Medicare & Medicaid Services] ["]CMS["] of its Best Prices with respect to Protonix Oral and Protonix IV. As a result of these submissions, Wyeth knowingly caused the States to present false and inflated claims for Medicaid payments to officials of the United States in violation of 31 U.S.C. § 3729(a)(1).

(Ex. 4 to Teva's Fourth Amended Answer and Counterclaims, Docket Entry No. 1054, ¶ 64). Count Two ("False Claims Act, 31 U.S.C. § 3729(a)(1)(B) (2009)") alleges:

> [F]or each quarter beginning with the second quarter of 2001, and continuing through the fourth quarter of 2006, Wyeth knowingly submitted false quarterly statements to CMS of its Best Prices on Protonix Oral and Protonix IV to reduce improperly its rebate obligations to the States under the MDRP. Wyeth's false quarterly statements of its Best Prices on Protonix Oral and Protonix IV caused the States to submit false and inflated submissions to the

> Federal Government for reimbursement of Medicaid expenditures in violation of 31 U.S.C. § 3729(a)(1)(B).

(*Id.*, ¶ 67). Count Three ("False Claims Act, 31 U.S.C. § 3729(a)(7)(1986)") alleges that:

> From the second quarter of 2001 and continuing through the fourth quarter of 2006, Wyeth knowingly made, used, and caused to be made and used, false records or statements to conceal, avoid, or decrease obligations to pay or transmit money or property to the government. Wyeth was aware of its obligation under the Rebate Statute, 42 U.S.C. § 1396r-8, to make and to use truthful records or statements regarding the Best Prices on Protonix Oral and Protonix IV. Wyeth also knew that its Best Price submissions would be used by the United States to calculate the unit rebate amount, which would affect the amount of the rebates that Wyeth was obligated to pay to the States for Protonix Oral and Protonix IV.

(*Id.*, ¶ 70). Count Four ("Common Law Fraud") alleges:

> From the second quarter of 2001 and continuing through the fourth quarter of 2006, Wyeth made and/or caused to be made fraudulent statements to the United States of its Best Prices on Protonix Oral and Protonix IV. Wyeth made and/or caused to be made these fraudulent material misrepresentations, failing to disclose material facts that it had a duty to disclose, with actual knowledge of the false and fraudulent nature of those misrepresentations and/or with reckless disregard for their truth.

(*Id.*, ¶ 74). Count Five ("Unjust enrichment") alleges that:

> Wyeth has been unjustly enriched by retaining the use and enjoyment of the monies that should have been paid to the States pursuant to the MDRP absent Wyeth's false and fraudulent misrepresentations regarding the Best Prices for Protonix Oral and Protonix IV.

(*Id.*, ¶ 79). And finally, Count Six ("Constructive Trust and Disgorgement") alleges that:

> By this claim, the United States requests a constructive trust and full accounting of all revenues (and interest thereon) and costs incurred by the Medicaid Program as a result of Wyeth submission of false Best Price reports and failure to comply with its obligations under the Medicaid Drug Rebate Statute and Rebate Agreement.

(*Id.*, ¶ 81).

Thus, it is clear that the legality of Wyeth's bundling strategy or hospital discounts is not something that will be decided in connection with the Massachusetts action or any of the False Claims Act cases. What is at issue in those cases is whether, *after* making sales of Protonix, Wyeth knowingly reported incorrect pricing data and, in doing so, failed to pay the proper amount of rebates to Medicaid. Even if the Massachusetts Court were ultimately to find that Wyeth, in fact, reported incorrect pricing data to Medicaid and, as a result, improperly reduced its rebate payments to Medicaid by hundreds of millions of dollars, this would provide no basis for finding the underlying Protonix sales illegal.[14]

Dr. Sullivan essentially concedes that the alleged "illegality" at issue in the Massachusetts action has no direct bearing on Wyeth's sales of Protonix as they relate to this action when he states that "I understand that Wyeth would not have implemented the bundled discounting strategy had the alleged Medicaid fraud not occurred." (Ruiz Decl., Ex. 14, ¶ 180). Defendants go on to theorize that "[a] jury reasonably could find . . . that if Wyeth had not engaged in the illegal activity, it would have sold substantially less Protonix." (Def. Opp'n Br. at 35-36).

While the Court agrees, as a general matter, that a plaintiff cannot recover lost profits that are predicated on the completion of illegal activity,[15] Defendants have put the cart before the horse. Not only has there been no finding, by any court, of Medicaid fraud by Wyeth, but also—and perhaps more importantly—there has been no finding that Wyeth's bundling strategy or

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[14] Defendants' request to stay the damages trial in this action pending a ruling or trial in the Massachusetts action is, therefore denied.

[15] *See, e.g., In re Gabapentin Patent Litig.*, No. 00-2931, 2011 WL 1807448, at *2 -3 (D.N.J. May 12, 2011) ("It is beyond dispute that [a plaintiff] cannot recover lost profits that are 'predicated on the completion of illegal activity.' ") (citations omitted).

hospital discounts were in any way illegal.[16] That issue is not before the Massachusetts Court, nor is it before this Court. Simply put, Defendants' theory of reducing damages based on Wyeth's *alleged* Medicaid fraud, and the effect that the *alleged* Medicaid fraud *may* have had on Wyeth's bundling strategy is, at this juncture, based on nothing more than pure speculation and unproven allegations. *See, e.g.*, Def. Opp'n Br. at 23 ("Wyeth funded this discount scheme by failing properly to report its discounts to the relevant Medicaid authorities, **as alleged in the Government's complaint.**") (emphasis added). In light of the foregoing, the Court agrees with Plaintiffs that no reasonable jury could conclude, based on Dr. Sullivan's report, that an award of damages in this matter should be reduced to account for those sales of Protonix attributable to Wyeth's bundling strategy. *See, e.g., Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1080 (Fed. Cir. 2005) ("A party does not manufacture more than a merely colorable dispute simply by submitting an expert declaration asserting that something is black when the moving party's expert says it is white; there must be some foundation or basis for the opinion."). Plaintiffs' motion for summary judgment on this issue is therefore **granted.**[17]

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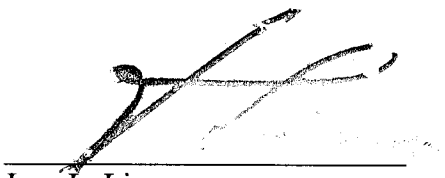
[16] This Court has already denied Defendants' attempt to assert the affirmative defense of patent misuse based on this bundling strategy. *See* Tr. (Sept. 29, 2011) at 12:16-25.

[17] Separate and apart from the issue of lost sales, in opposing Plaintiffs' motion, Defendants raise the issue that any finding of illegality (as to Wyeth's reporting practices vis-à-vis the Medicaid Drug Rebate Program) by the Massachusetts Court is relevant to the jury's determination of any reasonable royalty in this action. Defendants cite to *Georgia-Pacific Corp. v. United States Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970), for the proposition that one of the many factors that a court may consider in determining the amount of a reasonable royalty for a patent license is "[t]he portion of the realizable profit that should be credited to the invention as distinguished from non-patented elements . . . ." Based on this factor, Defendants argue that "Wyeth's unlawful schemes, which allowed Wyeth to expand its PPI market share, are a 'non-patented element' that tends to show that Protonix profits should not be attributed to the claimed invention; this unlawful conduct therefore warrants a lower royalty." (Def. Opp'n Br. at 28-29). Having considered Defendants' argument, the Court finds that, to the extent there is a ruling or final judgment entered in the Massachusetts action *before* the damages trial in this case is

CONCLUSION

For the reasons set forth above, Plaintiffs' motion for partial summary judgment seeking dismissal of Defendants' affirmative defense of *per se* patent misuse, as well as its "bundling" defense [Docket Entry No. 1121] is **granted**. Defendants' motion for summary judgment seeking a ruling that the patent-in-suit is unenforceable due to Plaintiffs' patent misuse [Docket Entry No. 1137] is **denied**.

An appropriate Order accompanies this Opinion.



Jose L. Linares
United States District Judge

Date: March 26, 2013

completed, Defendants may renew their request to introduce evidence of such ruling solely for the purpose of establishing a reasonably royalty. The Court will entertain any opposition by Plaintiffs at such time.